



Robert Essner
Chairman, President and CEO, Wyeth
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“The Patient Is Waiting”
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It's a great pleasure to speak with people who are on the front lines of aging about a subject that has very much been on my mind -- although having celebrated my 58th birthday recently, I've come to understand that I'm on the front lines of aging myself.

What's been on my mind is a topic in which we all have a vested interest: Alzheimer's disease.

This is an interesting time to be thinking about Alzheimer's and questioning whether we're prepared for the coming epidemic. I say “epidemic” because that's what we're headed for. An epidemic of enormous proportion. I am sure everyone in this room understands that better than most others.

I'm fairly certain, though, that the population at large does not really see Alzheimer's disease as an epidemic. Not yet.

If you were to say the word “epidemic” today, I'd bet that most people would immediately think first about avian flu, the so-called “bird flu.”

That's understandable because avian flu is getting massive attention in the media, and people are genuinely and understandably frightened by the possibility of this disease sweeping the world.

The projected mortality and morbidity from such a pandemic are indeed frightening. The CDC, the WHO and other organizations around the world have tracked every death from avian flu in humans since the mid-1990s. Researchers are working to understand avian influenza in the most minute detail and are mapping, with ever more intricate simulations, how the disease might spread if the feared mutation into a disease transmittable between humans were to occur.

So far, WHO has documented 135 people who have contracted avian flu in various parts of the world, primarily in Asia; 69 of them have died from it. My company, Wyeth, is one of the few vaccine research and development organizations in the world today so I've had the chance to see firsthand how we are confronting this potential pandemic on a global basis. In fact, the page 1 story in *The Wall Street Journal* this morning discussed the new avian flu vaccine for birds developed by Wyeth's veterinary division.

And although you can always argue that more could be done or that it could have been done sooner, the effort being made here in the United States and around the world is off to an impressive start. President Bush has clearly placed himself at the center of this endeavor; Health and Human Services Secretary Michael Leavitt has been designated to lead this task and is actively engaged. Public health officials and regulators

are beginning to work in a coordinated fashion among themselves and with Congress and industry to ensure that we are preparing ourselves as quickly as possible to limit the spread of avian flu and to arm ourselves with a supply of drugs and new vaccines that can be decisive. And, of course, the media is doing its job with a nearly obsessive focus on bird flu that keeps the topic front and center.

A Disease of Epidemic Proportions

With all the intensity and excitement being generated about avian influenza, I sometimes think we lose sight of the fact that this disease -- scary as it is -- is only a potential threat that we may or may not actually have to deal with. Unfortunately, unlike avian flu, there is little uncertainty about Alzheimer's disease. We know that an epidemic is coming - in fact, it's already here. We can predict with chilling accuracy its incidence and prevalence. We know the horrifying and ultimately fatal course of this illness. We know the collateral damage it does to the families of those who suffer from it. And we can project with reasonable precision the enormous financial toll that caring for the patients who suffer from it will take on our country's health care budget and our economy.

Sheldon Goldberg, former President and CEO of the Alzheimer's Association, made the following prediction:

"The U.S. health care system is about to implode, and Alzheimer's disease will be the detonator. ... You will not – you cannot – save

Medicare and Medicaid unless you get this disease under control. The cost of long-term care will bankrupt families first. And then it will bankrupt Medicaid.”

What Sheldon Goldberg was referring to is the coming collision between the enormous baby boom generation now entering its 60s and our national health care budget. You can see the train wreck coming: An estimated 4.5 million Americans have Alzheimer’s disease -- double the number since 1980. This year, 470,000 new patients in the U.S. have been confronted with the dehumanizing reality of Alzheimer’s disease. And that number will increase every year from now on. In addition, more than 50 percent of individuals who are 85 years of age or older are afflicted with Alzheimer’s disease.

You’ve probably heard these statistics before. But you may not have heard that national direct and indirect costs of caring for individuals with Alzheimer’s disease are at least \$100 billion per year, according to estimates used by the Alzheimer’s Association and the National Institute on Aging.

And I imagine that Dr. Mark McClellan, who spoke with you earlier this afternoon, is well aware of the projection that annual Medicare costs for beneficiaries with Alzheimer’s are expected to increase 75 percent over the next five years -- from \$91 billion in 2005 to \$160 billion in 2010.

I think you get the picture.

What is so horrifying about Alzheimer's is not just that it kills but that it is debilitating and dehumanizing. Alzheimer's essentially eats away at the very essence of its victims: not just their physical and mental capabilities -- but also their hearts and souls.

Wyeth's Scientists Eagerly Begin Research

Because Wyeth is involved in the fight against Alzheimer's, I have a kind of front row seat in our efforts against this disease. Wyeth's research efforts in Alzheimer's began in earnest in the year 2000, when a group of our scientists came to me with a proposal. They wanted to enter into a collaboration with another much smaller company to advance a new technology against Alzheimer's. The team told me that this was, in their opinion, the single best approach to creating a really effective treatment for this disease and that they thought it had the highest chance of success of anything in development. I, of course, had to ask a few questions.

First, why were they so enthusiastic and why did they think we had any chance of success in a disease that had proved so elusive? They explained that this technology was aimed at quickly ridding the brain of the beta amyloid plaque that was -- and still is -- thought to be an important causal factor in Alzheimer's and that the work done so far on this principle in animal studies had produced the most dramatic results ever seen in these types of tests. So I asked them how long it would take before we would have any real idea about whether or not this would be useful in people because we all know that animal work, particularly in

diseases involving the brain, is not very predictive. They told me that they expected it would take about three more years of research effort before they would know whether the project could move into full-scale development. Then I asked them a critical question: How much would we have to spend over those three years to get even a preliminary appraisal of efficacy? After a little hemming and hawing, they told me they thought it could cost up to \$100 million to do those studies.

Then I asked the really hard question: If we invested that much money over the next three years, what was the probability that when we were done with that work the answer would be “yes” -- that we would have sufficient evidence that the drug works and is safe enough to move into the large-scale studies necessary for approval. This brought a lot more hemming and hawing and a little shuffling about until someone said “maybe 30 percent probability of success” -- to which I responded, “Really!” Then someone said, “Well, maybe it’s more like 10 percent.” When I challenged that, the real answer came out -- which was that the odds of success were so low that no one could say what they were. However, we made the decision to go ahead -- our scientists were so passionate that if I had turned them down, I would have had a mutiny.

Wyeth created a partnership with the Irish company, Elan. It was an unprecedented effort in that, for the first time, we brought together scientists from Wyeth’s three research divisions. We asked leaders from our central nervous system drug discovery and development units to work in day-to-day collaboration with some of our leading biotechnology specialists and experts from our vaccine research effort.

The problem-solving abilities of these scientists, together with those of our partner, have brought to this project the unusually broad array of scientific tools and creativity that have kept us going. More than five years have gone by since we made our decision, and about all we can say after five years of effort is that this program still has the tantalizing possibility of success. Our first drug candidate was stopped when we saw some early signs of a safety issue in a few patients. But we're back with two additional approaches, an antibody which is now in Phase 2 clinical studies in Alzheimer's patients and a vaccine approach, just now starting in clinical research.

And by the way, that \$100 million estimate has long ago been spent -- and, in fact, our partnership has invested well over \$200 million, and, unfortunately, we're still closer to the beginning than the end. Either of these programs has the potential to be the kind of new tool we need to treat or even prevent Alzheimer's if we get really lucky. But risks are high, and, in the current environment, we are still probably at least five years away from introducing an approved therapy to patients. And I can tell with complete candor that if this were a program in virtually any other disease, it would have been terminated years ago.

The power of this disease and the challenge of conquering it drives us on. Wyeth and Elan obviously are not alone on this path in trying to find a solution for Alzheimer's; there are other companies also at work, as well as scientists in academia and research institutes who are making their own contributions.

Small Steps Create Reasons for Optimism

Although there are reasons for hope -- our better understanding of the disease and its progression, better diagnostic tools and some modestly useful therapies available today -- the reality is that our efforts against Alzheimer's are moving at a pace that is in no way commensurate with the problem we're trying to solve. Unlike my example of avian flu, there is no global focus. Scientific work and drug development go on but at a snail's pace. Public health agencies sometimes appear to be focused more on dealing with the seemingly inevitable devastation of the disease than in working toward its cure. And regulatory agencies like the FDA handle the review of Alzheimer's projects more like the cautious and arm's length way they review new anti-hypertensives rather than in the accelerated and collaborative way they handle drugs for HIV/AIDS or bird flu. On the regulatory front alone, worldwide cooperation between reviewers and researchers could significantly improve the probability that we do succeed and reduce development time lines by years.

There are always issues with moving more quickly: Speed places increased pressure on all involved. But given the mounting toll this disease is taking every year, we have no other choice.

Our collective efforts against HIV/AIDS give us another instructive example of what can be done. In the war against AIDS, government, regulatory agencies, scientists in industry and academia, and patient groups worked hand in hand to develop new therapies and evaluate them as rapidly as possible. The results were remarkable. AIDS was

first identified around 1980, and just six years later, there was a breakthrough medication that helped people manage the symptoms. Today, there are dozens of medications to treat this disease and many more on the way. For many patients with AIDS, these medications have transformed the disease from a death sentence to a chronic condition. The war has not been won with AIDS, but we have made significant progress.

Knowing all of this, how do we convince the world that Alzheimer's is the next pandemic? Public awareness of the disease is high -- and so, too, are assumptions and misconceptions. Unlike avian flu, which has popped up in the public eye over a relatively short period of time, a disease like Alzheimer's has been known for generations. Too many people still believe that "it's a natural process" or "it's just a part of growing old" or "there's nothing much to be done."

We've all known someone -- a parent, an aunt, an uncle -- who has fallen prey to this disease. A recent Gallup Poll found that nearly 50 percent of respondents worry about developing Alzheimer's. However, instead of spurring people into action, this knowledge seems to engender a sense of resignation, of inevitability.

On the other end of the age scale, my teenage son, Ben, isn't too worried about Alzheimer's but gets his thrills by watching action movies. We recently saw "Deep Impact," a disaster film of epic proportions: a seven-mile-wide rock is hurtling through space, its course bound straight for earth. If you haven't seen this particular film, you've seen one like it.

Within days of the discovery of the asteroid, everyone on the planet knows it will be the end of life as we know it when the asteroid finally hits earth. The fact that it's not going to happen tomorrow doesn't make any difference -- public concern demands a solution. As always in these films, through a mixture of massive effort, new technology, individual heroism and many theater-shaking explosions, the earth is saved.

In much the same way, Alzheimer's should be our health care "asteroid." We know it's an enormous threat -- and we know it's coming. We know the fears we all share should Alzheimer's strike us or, worse yet, someone we love.

What we lack is a worldwide clamor for immediate action and a solution - - we need to generate a sense of urgency because, even with the best of luck, the answer won't come overnight. We need to start now. Those of you in this room are serving on the front lines; we need your leadership, your voice, your passion to turn this around.

We have a saying in my industry that we use from time to time when the going gets tough, when we find ourselves caught up in the frustrations of a process that is, by its nature, slow and prone to failure. That saying is "The patient is waiting." I know of no disease in our country where more patients are waiting with so much need and so little hope. And I came here this afternoon to tell you it does not have to be so.

Thank you.